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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/596,086	06/16/2000	Elfi Biedermann	69054	3172

22242 7590 03/22/2004

FITCH EVEN TABIN AND FLANNERY  
120 SOUTH LA SALLE STREET  
SUITE 1600  
CHICAGO, IL 60603-3406

EXAMINER
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COLEMAN, BRENDA LIBBY

ART UNIT	PAPER NUMBER
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1624

DATE MAILED: 03/22/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No. 09/596,086	Applicant(s) BIEDERMANN ET AL.	
	Examiner Brenda L. Coleman	Art Unit 1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 12 December 2003.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 55-77 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 55-77 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

### **DETAILED ACTION**

Claims 55-77 are pending in the application.

This action is in response to applicant's amendment filed December 12, 2003.

Claims 55-58, 60 and 69-77 have been amended.

### ***Response to Amendment***

Applicant's amendments and arguments filed December 12, 2003 have been fully considered with the following effect:

1. With regards to the objection to the Information Disclosure Statement the applicants stated that a Supplemental IDS that addresses the objections raised by the Examiner is submitted herewith. However, a Supplemental IDS was not received.

The information disclosure statement filed January 4, 2001 fails to comply with the provisions of 37 CFR 1.97, 1.98 and MPEP ' 609 because the first citation under the heading OTHER DOCUMENTS is incomplete and not in the English language. The reference to this article fails to include the Arthur, title, date, volume, number, pertinent pages, etc. The article is also in a language which the examiner cannot understand and hence cannot be considered. It has been placed in the application file, but the information referred to therein has not been considered as to the merits. Applicant is advised that the date of any re-submission of any item of information contained in this information disclosure statement or the submission of any missing element(s) will be the date of submission for purposes of determining compliance with the requirements based on the time of filing the statement, including all certification requirements for statements under 37 CFR 1.97(e). See MPEP ' 609 & C(1).

It is also noted that there are three Chemical Abstracts listed under the heading OTHER DOCUMENTS where there is no indication what the chemical abstract number is. For example, the first Chemical Abstract listed is Vol. 124, No. 13, 1996, but there are citations on the page provided, i.e. 124:173007q, 124:173008r, 124:173009s, 124:173010k, 124:173011m, 124:173012n, 124:173013p, 124:173014q, 124:173015r and part of 124:173016s. It is also noted that the applicants have recited a Rote Liste, however, it is not known what is meant by the Rote Liste, 1997 which is the last citation under the heading OTHER DOCUMENTS.

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2. The applicants amendments and arguments are sufficient to overcome the 35 U.S.C. § 112, second paragraph rejection of claim 58, labeled paragraph 4) maintained in the last office action, which is hereby **withdrawn**.

3. The applicant's amendments and arguments are sufficient to overcome the 35 U.S.C. § 102, anticipation rejection labeled paragraph 5) maintained in the last office action, which is hereby **withdrawn**.

4. The applicant's amendments and arguments are sufficient to overcome the 35 U.S.C. § 112, second paragraph rejections labeled paragraph 7 c), e), f), av), ax), az), ba), be), bf), bh) and bi) maintained in the last office action, which are hereby **withdrawn**.

5. The applicant's amendments and arguments are sufficient to overcome the 35 U.S.C. § 112, first paragraph rejection labeled paragraph 8) in the last office action, which is hereby **withdrawn**.

6. The applicant's amendments and arguments are sufficient to overcome the 35 U.S.C. § 112, first paragraph rejection labeled paragraph 9) in the last office action, which is hereby **withdrawn**.

7. The applicant's amendments and arguments are sufficient to overcome the 35 U.S.C. § 112, second paragraph rejections labeled paragraph 10) in the last office action, which are hereby **withdrawn**.

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8. The applicant's arguments are sufficient to overcome the 35 U.S.C. § 102, anticipation rejection labeled paragraph 11) in the last office action, which is hereby **withdrawn**.

9. The applicant's arguments are sufficient to overcome the 35 U.S.C. § 102, anticipation rejection labeled paragraph 12) in the last office action, which is hereby **withdrawn**.

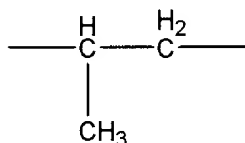
10. The applicant's amendments and arguments are sufficient to overcome the 35 U.S.C. § 102, anticipation rejection labeled paragraph 13) in the last office action, which is hereby **withdrawn**.

11. With regards to the 35 U.S.C. § 102, anticipation rejection labeled paragraph 14 of the last office action, the applicant's amendments and remarks have been fully considered but they are not persuasive. The applicants stated that Saito et al. cannot anticipate the compounds and compositions of the present invention because D cannot represent  $-\text{CH}(\text{CO}_2\text{H})-\text{CH}_2-\text{CH}_2-$  as carboxylic acid does not represent a substituent of the  $\text{C}_3\text{-C}_{12}$ -alkylene group. The definition of D is such that D is selected from the group consisting of  $\text{C}_3\text{-C}_{12}$ -alkylene, a substituted  $\text{C}_3\text{-C}_{12}$ -alkylene which is substituted once or twice by  $\text{C}_1\text{-C}_6$ -alkyl, hydroxy,  $\text{C}_1\text{-C}_6$ -alkoxy or phenyl,  $\text{C}_3\text{-C}_{12}$ -alkenylene, a substituted  $\text{C}_3\text{-C}_{12}$ -alkenylene which is substituted once or twice by  $\text{C}_1\text{-C}_6$ -alkyl, hydroxy,  $\text{C}_1\text{-C}_6$ -alkoxy or phenyl,  $\text{C}_5\text{-C}_{12}$ -alkadienylene, substituted  $\text{C}_5\text{-C}_{12}$ -alkadienylene which is substituted once or twice by  $\text{C}_1\text{-C}_6$ -alkyl, hydroxy,  $\text{C}_1\text{-C}_6$ -alkoxy or phenyl,  $\text{C}_3\text{-C}_{12}$ -alkynylene, a substituted  $\text{C}_3\text{-C}_{12}$ -alkynylene which is substituted once or twice by  $\text{C}_1\text{-C}_6$ -

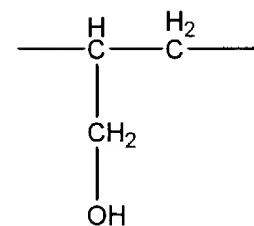
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alkyl, hydroxy, C<sub>1</sub>-C<sub>6</sub>-alkoxy or phenyl, C<sub>5</sub>-C<sub>12</sub>-alkeninylene, a substituted C<sub>5</sub>-C<sub>12</sub>-alkeninylene which is substituted once or twice by C<sub>1</sub>-C<sub>6</sub>-alkyl, hydroxy, C<sub>1</sub>-C<sub>6</sub>-alkoxy or phenyl, and C<sub>3</sub>-C<sub>12</sub>-alkylene, C<sub>3</sub>-C<sub>12</sub>-alkenylylene or C<sub>3</sub>-C<sub>12</sub>-alkinylylene, wherein, with the exception of the (G)-terminal methylene group in the C<sub>3</sub>-C<sub>12</sub>-alkylene, C<sub>3</sub>-C<sub>12</sub>-alkenylylene or C<sub>3</sub>-C<sub>12</sub>-alkinylylene, one to three methylene units in the C<sub>3</sub>-C<sub>12</sub>-alkylene, C<sub>3</sub>-C<sub>12</sub>-alkenylylene or C<sub>3</sub>-C<sub>12</sub>-alkinylylene are isosterically replaced by O, S, NR<sup>7</sup>, CO, SO or SO<sub>2</sub>, wherein R<sup>7</sup> is selected from the group consisting of hydrogen, C<sub>1</sub>-C<sub>6</sub>-alkyl, C<sub>1</sub>-C<sub>6</sub>-alkenyl, C<sub>1</sub>-C<sub>6</sub>-acyl, and C<sub>1</sub>-C<sub>6</sub>-alkanesulfonyl. Saito teaches D where D is as follows:

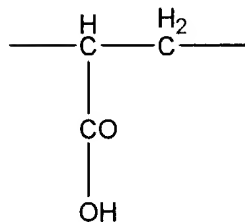
- a. D is C<sub>3</sub>-alkylene, i.e.



- b. Substituted by OH, i.e.



- c. With the exception of the (G)-terminal methylene group in the C<sub>3</sub>-alkylene, one methylene unit in the C<sub>3</sub>-alkylene is isosterically replaced by CO, i.e.



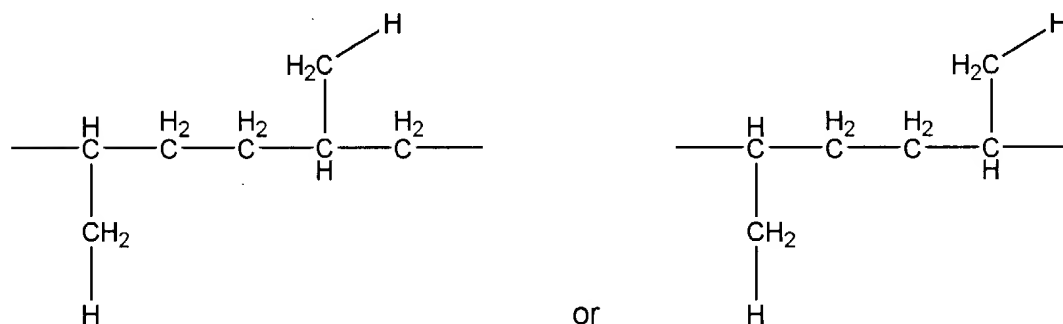
- d. the end product as taught by Saito, i.e. -CH(CO<sub>2</sub>H)-CH<sub>2</sub>-

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Claims 55, 60 and claims dependent thereon are rejected under 35 U.S.C.

102(b) as being anticipated by Saito et al., (J. Enzyme Inhib.) for reasons of record and stated above.

12. With regards to the 35 U.S.C. § 102, anticipation rejection labeled paragraph 15 of the last office action, the applicant's amendments and remarks have been fully considered but they are not persuasive. The applicants stated that Koenig et al. cannot anticipate the compounds and compositions of the present invention because D cannot be  $-\text{CH}(\text{CH}_2\text{Obu-t})-\text{C}(\text{O})-\text{NH}-\text{CH}(\text{CO}_2\text{Bu-t})-$  as  $\text{C}_3\text{-C}_{12}$ -alkylene group in the definition of D may not be substituted neither by t-butoxymethyl nor by t-butoxycarbonyl. However, as shown above the  $\text{C}_3\text{-C}_{12}$ -alkylene group is

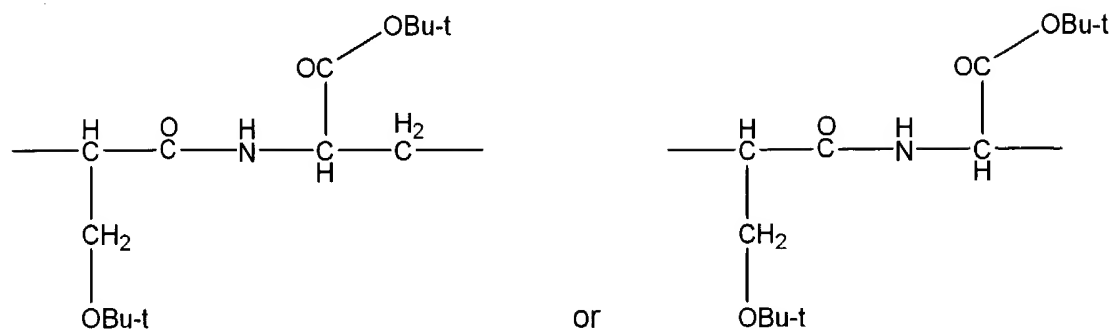


where G is  $-\text{CH}_2\text{-Ph}$

where G is Ph;

two hydrogen atoms of each are then substituted by  $\text{C}_1\text{-C}_6$  alkoxy groups, i.e.  $-\text{Obu-t}$ ; and with the exception of the (G)-terminal methylene group in the  $\text{C}_3\text{-C}_{12}$ -alkylene, three methylene units in the  $\text{C}_3\text{-C}_{12}$ -alkylene are isosterically replaced by CO, NH and CO; the end product is as follows:

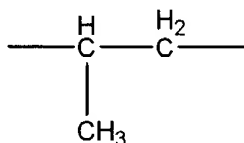
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where G is  $-\text{CH}_2\text{-Ph}$ 

where G is Ph as taught by Koenig.

Claims 55, 60 and claims dependent thereon are rejected under 35 U.S.C. 102(b) as being anticipated by Koenig et al., EP 477 499, for reasons of record and stated above.

13. With regards to the 35 U.S.C. § 102, anticipation rejection labeled paragraph 16 of the last office action, the applicant's amendments and remarks have been fully considered but they are not persuasive. The applicants stated that Hashimoto et al. does not anticipate the compounds and compositions of the present invention because D cannot be  $-\text{CH}(\text{CO}_2\text{H})\text{-CH}_2-$  as D does not comprise a  $\text{C}_2$ -alkylene and also may not be substituted by a carboxylic acid group. However, as shown above the  $\text{C}_3\text{-C}_{12}$ -alkylene group is where D is  $\text{C}_3$ -alkylene, i.e.



where the  $\text{CH}_3$  group is substituted by a hydroxy group and the  $\text{CH}_2$  of the  $\text{CH}_3$  is isosterically replaced by CO.

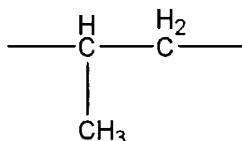


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Claims 55, 60 and claims dependent thereon are rejected under 35 U.S.C.

102(b) as being anticipated by Hashimoto et al., Pharm. Res., for reasons of record and stated above.

14. With regards to the 35 U.S.C. § 102, anticipation rejection labeled paragraph 17 of the last office action, the applicant's amendments and remarks have been fully considered but they are not persuasive. The applicants stated that Kukkoa et al. does not anticipate the compounds and compositions of the present invention because D cannot be  $-\text{CH}_2(\text{CH}_2\text{-SH})\text{-CH}_2-$  as D does not comprise  $\text{C}_2$ -alkylene, nor may it be substituted by thiomethyl. However, as shown above the  $\text{C}_3\text{-C}_{12}$ -alkylene group is where D is  $\text{C}_3$ -alkylene, i.e.



where the  $\text{CH}_2$  of the  $\text{CH}_3$  is isosterically replaced by S.

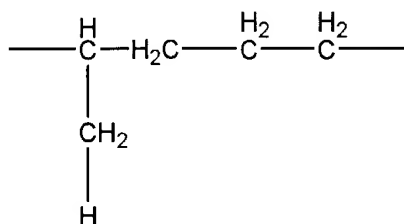
Claims 55, 60 and claims dependent thereon are rejected under 35 U.S.C.

102(b) as being anticipated by Kukkola et al., Bioorg. Med. Chem. Lett., for reasons of record and stated above.

15. With regards to the 35 U.S.C. § 102, anticipation rejection labeled paragraph 18 of the last office action, the applicant's amendments and remarks have been fully considered but they are not persuasive. The applicants stated that Itoh et al. does not anticipate the compounds and compositions of the present invention because D cannot be  $-\text{CH}(\text{CH}_2\text{-Ph})\text{-C(O)-N}(\text{CH}_3)\text{-}$  as (i)  $\text{C}_3\text{-C}_{12}$ -alkylene may not be substituted by a

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benzyl and (ii) and isosteric replacement may not occur for the (G)-terminal methylene group. However, as shown above the C<sub>3</sub>-C<sub>12</sub>-alkylene group is where D is C<sub>5</sub>-alkylene, i.e.

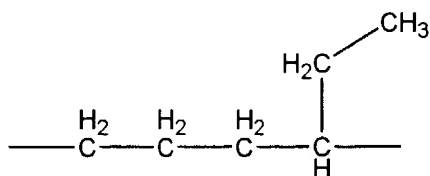


where the CH<sub>3</sub> group is substituted by a phenyl group and the H<sub>2</sub>C methylene unit is isosterically replaced by CO and the methylene unit adjacent is replaced by N(CH<sub>3</sub>).

Claims 55, 60 and claims dependent thereon are rejected under 35 U.S.C.

102(b) as being anticipated by Itoh et al., WO 96/16981, for reasons of record and stated above.

16. With regards to the 35 U.S.C. § 102, anticipation rejection labeled paragraph 19 of the last office action, the applicant's amendments and remarks have been fully considered but they are not persuasive. The applicants stated that Adams et al. does not anticipate the compounds, compositions and method of use of the compounds of the present invention because D cannot be -CH(I-Bu)-CO-NH-CH(CH<sub>2</sub>-CO<sub>2</sub>H)- as D for the definition of C<sub>3</sub>-C<sub>12</sub>-alkylene may neither be substituted by (i) isobutyl nor by (ii) CH<sub>2</sub>-CO<sub>2</sub>H. However, as shown above the C<sub>3</sub>-C<sub>12</sub>-alkylene group is

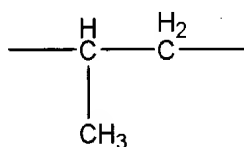


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where the first CH<sub>2</sub> group is substituted by isobutyl or may be C<sub>4</sub>-alkylene of the C<sub>3</sub>-C<sub>12</sub>-alkylene group; the second and third methylene units are isosterically replaced by CO and NH, respectively and the CH<sub>3</sub> group is substituted by a hydroxy group and the CH<sub>2</sub> of the CH<sub>3</sub> is isosterically replaced by CO.

Claims 55, 60, 70, 71 and claims dependent thereon are rejected under 35 U.S.C. 102(b) as being anticipated by Adams et al., WO 96/22966, for reasons of record and stated above.

17. With regards to the 35 U.S.C. § 102, anticipation rejection labeled paragraph 20 of the last office action, the applicant's amendments and remarks have been fully considered but they are not persuasive. The applicants stated that Myers et al. does not anticipate the compounds of the present invention because D cannot represent – CH<sub>2</sub>(CH<sub>3</sub>)-CH(OH)- as the definition for D does not allow C<sub>2</sub>-alkylene (which may be substituted). However, as shown above the C<sub>3</sub>-C<sub>12</sub>-alkylene group is where D is C<sub>3</sub>-alkylene, i.e.



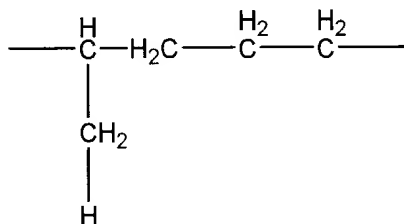
where the CH<sub>2</sub> group is substituted by a hydroxy.

Claims 55 and claims dependent thereon are rejected under 35 U.S.C. 102(b) as being anticipated by Myers et al., J. Am. Chem. Soc., for reasons of record and stated above.

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18. The applicant's amendments and arguments are sufficient to overcome the 35 U.S.C. § 102, anticipation rejection labeled paragraph 21) in the last office action, which is hereby **withdrawn**.

19. With regards to the 35 U.S.C. § 102, anticipation rejection labeled paragraph 22 of the last office action, the applicant's amendments and remarks have been fully considered but they are not persuasive. The applicants stated that Audia et al. cannot anticipate the compounds and compositions of the present invention because D cannot be  $-\text{CH}(\text{CH}_3)-\text{C}(\text{O})-\text{NH}-\text{CH}(\text{CO}-\text{O}-\text{CH}_3)-$  as the definition of D does not allow a substitution by methoxycarbonyl. However, as shown above the  $\text{C}_3-\text{C}_{12}$ -alkylene group is where D is  $\text{C}_5$ -alkylene, i.e.

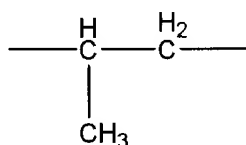


where the  $\text{CH}_3$  group is substituted by a methoxy group and the  $\text{CH}_2$  methylene unit is isosterically replaced by CO; and the methylene unit on the end is substituted by a methyl group, the methylene unit adjacent to the terminal one is replaced by CO and the methylene unit adjacent to the CO is replaced by NH. This is just one interpretation of D where G is  $-\text{CH}_2-\text{Ph}$ , however, the  $\text{CH}_2$  of G could also be part of D as well as the methyl substituted on the terminal methylene unit.

Claims 55, 60 and claims dependent thereon are rejected under 35 U.S.C. 102(a) as being anticipated by Audia et al., WO 98/22494, for reasons of record and stated above.

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20. With regards to the 35 U.S.C. § 102, anticipation rejection labeled paragraph 23 of the last office action, the applicant's amendments and remarks have been fully considered but they are not persuasive. The applicants stated that Santangelo et al. cannot anticipate the compounds and compositions of the present invention because D may not be  $-\text{CH}(\text{CO}_2\text{H})-\text{CH}_2-$  as the definition for D does not allow  $\text{C}_2$ -alkylene nor does it allow the substitution by a carboxylic acid group. However, as shown above the  $\text{C}_3$ - $\text{C}_{12}$ -alkylene group is where D is  $\text{C}_3$ -alkylene, i.e.

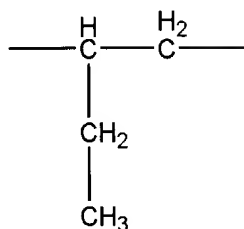


where the  $\text{CH}_3$  group is substituted by a hydroxy and the methylene unit of the  $\text{CH}_3$  is isosterically replaced by CO.

Claims 55, 60 and claims dependent thereon are rejected under 35 U.S.C. 102(a) as being anticipated by Santangelo et al., U.S. Patent No. 5,760,241, for reasons of record and stated above.

21. With regards to the 35 U.S.C. § 102, anticipation rejection labeled paragraph 24 of the last office action, the applicant's amendments and remarks have been fully considered but they are not persuasive. The applicants stated that Hayes et al. cannot anticipate the compounds and compositions of the present invention because D cannot represent  $-\text{CH}(\text{CONH}_2)-\text{CH}_2-$  as D may not be  $\text{C}_2$ -alkylene, nor may it be substituted by aminocarbonyl. However, as shown above the  $\text{C}_3$ - $\text{C}_{12}$ -alkylene group is where D is  $\text{C}_4$ -alkylene, i.e.

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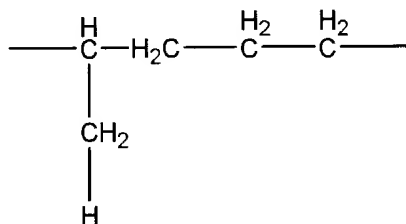


where the methylene unit of the CH<sub>3</sub> group is isosterically replaced by NH and the methylene unit adjacent to the CH<sub>3</sub> group is isosterically replaced by CO.

Claims 55, 60 and claims dependent thereon are rejected under 35 U.S.C.

102(a) as being anticipated by Hayes et al., WO 98/34111, for reasons of record and stated above.

22. With regards to the 35 U.S.C. § 102, anticipation rejection labeled paragraph 25 of the last office action, the applicant's amendments and remarks have been fully considered but they are not persuasive. The applicants stated that Palmer et al. cannot anticipate the compounds of the present invention because D may not be -CH(CH<sub>2</sub>OH)-C(O)- as D cannot be substituted by hydroxymethyl. However, as shown above the C<sub>3</sub>-C<sub>12</sub>-alkylene group is where D is C<sub>5</sub>-alkylene, i.e.

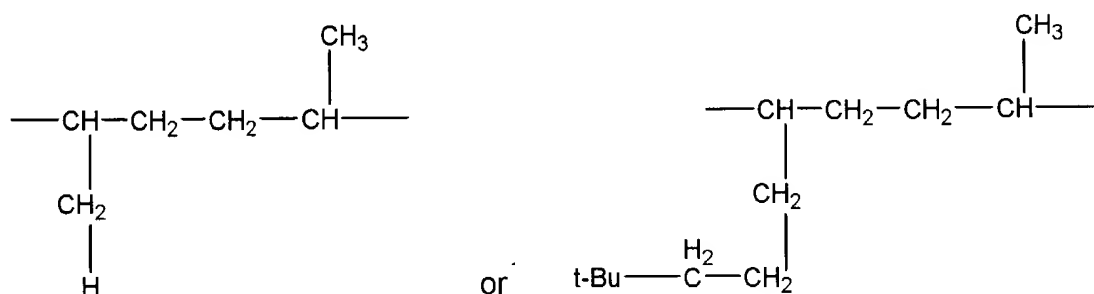


where the CH<sub>3</sub> group is substituted by a hydroxy group; and the methylene unit adjacent to the one on the end is isosterically replaced by O and the methylene unit adjacent to the O is replaced by CO.

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Claims 55 and claims dependent thereon are rejected under 35 U.S.C. 102(e) as being anticipated by Palmer et al., U.S. Patent No. 5,977,302, for reasons of record and stated above.

23. With regards to the 35 U.S.C. § 102, anticipation rejection labeled paragraph 26 of the last office action, the applicant's amendments and remarks have been fully considered but they are not persuasive. The applicants stated that Sham et al. cannot anticipate the compounds, compositions and method of use of the compounds of the present invention because D can neither be  $-\text{CH}(\text{CH}_2\text{-Ph})\text{-CH}(\text{OH})\text{-CH}_2\text{-CH}(\text{NH-CO-OBu-t})-$  nor  $-\text{CH}(\text{CH}_2\text{Ph})\text{-CH}(\text{OH})\text{-CH}_2\text{-CH}(\text{NH}_2)-$ . The definition of D does not allow the substitution with any of the following residues: benzyl, t-butoxycarbonylamino or amino. However, as shown above the  $\text{C}_3\text{-C}_{12}$ -alkylene group is where D is  $\text{C}_6$ -alkylene or  $\text{C}_{12}$ -alkylene, i.e.

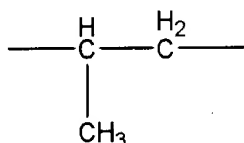


where the  $\text{CH}_3$  group is substituted by a phenyl group and the methylene unit attached to the CH is substituted by hydroxy; the methylene unit adjacent to the t-Bu is isosterically replaced by O and the methylene unit adjacent to the O is replaced by CO and the methylene unit adjacent to the CO is replaced by NH. This is just one interpretation of D where G is  $-\text{CH}_2\text{-Ph}$ , however, the  $\text{CH}_2$  of G could also be part of D as well as the methyl substituted on the terminal methylene unit.

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Claims 55, 60, 71 and claims dependent thereon are rejected under 35 U.S.C. 102(b) as being anticipated by Sham et al., WO 97/21685, for reasons of record and stated above.

24. With regards to the 35 U.S.C. § 102, anticipation rejection labeled paragraph 27 of the last office action, the applicant's amendments and remarks have been fully considered but they are not persuasive. The applicants stated that Abelman et al. cannot anticipate the compounds and compositions of the present invention because A not be  $-\text{CH}_2-\text{CH}(\text{NH}_2)-$  because the definition of A does not allow an isosteric substitution adjacent to the amide group. However, as shown above for the definition of D the  $\text{C}_1-\text{C}_6$ -alkylene group of A is where A is  $\text{C}_3$ -alkylene, i.e.



where the methylene unit of the  $\text{CH}_3$  group is isosterically replaced by  $\text{NH}$ .

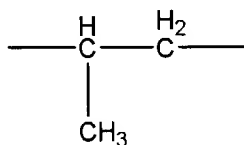
Claims 55, 60 and claims dependent thereon are rejected under 35 U.S.C. 102(b) as being anticipated by Abelman et al., WO 96/19493, for reasons of record and stated above.

25. With regards to the 35 U.S.C. § 102, anticipation rejection labeled paragraph 28 of the last office action, the applicant's amendments and remarks have been fully considered but they are not persuasive. The applicants stated that Hu et al. cannot anticipate the compounds and compositions of the present invention because A cannot be  $-\text{CH}_2-\text{CH}(\text{NH}-\text{CH}_2-\text{CH}_2-\text{CH}(\text{CH}_3)_2)-$ ,  $-\text{CH}_2-\text{CH}(\text{N}(\text{Me})-(\text{CH}_2-\text{CH}_2-\text{CH}(\text{CH}_3)_2))-$ ,  $-\text{CH}_2-$



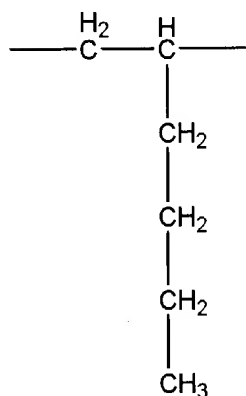
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$\text{CH}(\text{N}(\text{Me})(\text{i-Bu}))$ -,  $-\text{CH}_2-\text{CH}(\text{N}(\text{Me})\text{CH}_2-\text{CH}_2-\text{CH})(\text{CH}_3)_2$ -, and  $-\text{CH}_2-\text{CH}(\text{NH}_2)$ -. The following substitutions are not allowed: isopentylamino, isopentyl-methylamino, isobutyl-methylamino or amino. However, as shown above for the definition of D the  $\text{C}_1$ - $\text{C}_6$ -alkylene group of A is where A is  $\text{C}_3$ -alkylene, i.e.



where the methylene unit of the  $\text{CH}_3$  group is isosterically replaced by  $\text{NH}$ , for the species where A contains an amino group;

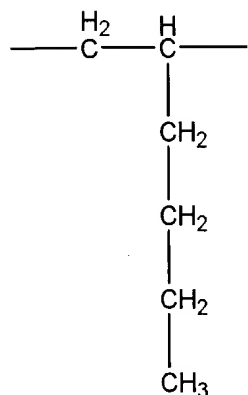
A is  $\text{C}_6$ -alkylene, i.e.



where the methylene unit attached to the  $\text{CH}$  is isosterically replaced by  $\text{NH}$  and the  $\text{CH}_3$  is substituted by two methyl groups, for the species where A contains an isopentylamino;

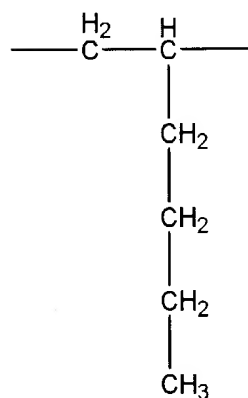
A is  $\text{C}_6$ -alkylene, i.e.

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where the methylene unit attached to the CH is isosterically replaced by N(CH<sub>3</sub>) and the CH<sub>3</sub> is substituted by two methyl groups, for the species where A contains an isopentyl-methylamino;

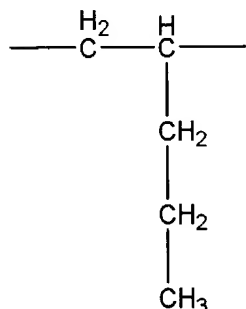
A is C<sub>6</sub>-alkylene, i.e.



where the methylene unit attached to the CH is isosterically replaced by N(CH<sub>3</sub>) and the CH<sub>3</sub> is substituted by three methyl groups, for the species where A contains an isobutylethyl-methylamino;

A is C<sub>5</sub>-alkylene, i.e.

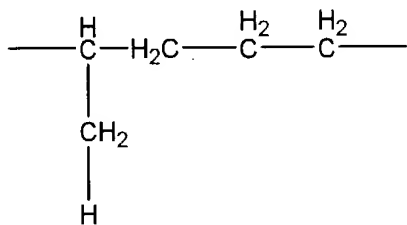
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where the methylene unit attached to the CH is isosterically replaced by N(CH<sub>3</sub>) and the CH<sub>3</sub> is substituted by two methyl groups, for the species where A contains an isobutyl-methylamino.

Claims 55, 60 and claims dependent thereon are rejected under 35 U.S.C. 102(e) as being anticipated by Hu et al., U.S. Patent No. 6,166,052, for reasons of record and stated above.

26. With regards to the 35 U.S.C. § 102, anticipation rejection labeled paragraph 29 of the last office action, the applicant's amendments and remarks have been fully considered but they are not persuasive. The applicants stated that Wu et al. does not anticipate the compounds and compositions of the present invention because cannot represent -CH(CH<sub>3</sub>)-C(O)-NH-CH(CO<sub>2</sub>Me)- as C<sub>3</sub>-C<sub>12</sub>-alkylene in the definition of D may not be substituted by methoxycarbonyl. However, as shown above the C<sub>3</sub>-C<sub>12</sub>-alkylene group is where D is C<sub>5</sub>-alkylene, i.e.



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where the CH<sub>3</sub> group is substituted by a methoxy group and the CH<sub>2</sub> methylene unit is isosterically replaced by CO; and the methylene unit on the end is substituted by a methyl group, the methylene unit adjacent to the terminal one is replaced by CO and the methylene unit adjacent to the CO is replaced by NH. This is just one interpretation of D where G is -CH<sub>2</sub>-Ph, however, the CH<sub>2</sub> of G could also be part of D as well as the methyl substituted on the terminal methylene unit.

Claims 55, 60 and claims dependent thereon are rejected under 35 U.S.C. 102(e) as being anticipated by Wu et al., U.S. Patent No. 6,191,166, for reasons of record and stated above.

In view of the amendment dated December 12, 2003, the following new grounds of rejection apply:

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

27. Claim 73 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The applicant's amendment to claim 73 where the reactive holgenated derivatives of an alcohol was amended to reactive derivatives of an alcohol is not described in the specification.

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Applicant is required to cancel the new matter in the reply to this Office action.

28. Claim 74 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The applicant's amendment to claim 74 where G is  $-(CH_2)_n-(CR^9R^{10})_m-R^8$  is not described in the specification with respect to the genus.

Applicant is required to cancel the new matter in the reply to this Office action.

29. Claim 75 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The applicant's amendment to claim 75 where the definition of m, i.e. m is 0 or 4 was insert is not described in the specification.

Applicant is required to cancel the new matter in the reply to this Office action.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

30. Claims 55, 56 and 58-75 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The following reasons apply:

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a) Claim 55 is vague and indefinite in that it is not known what is meant by the capital letter "G" in Group, see the ninth line from the bottom of page 9.

608.01(m) Form of Claims [R - 3]

The claim or claims must commence on a separate sheet and should appear after the detailed description of the invention. While there is no set statutory form for claims, the present Office practice is to insist that each claim must be the object of a sentence starting with "I (or we) claim", "The invention claimed is" (or the equivalent). If, at the time of allowance, the quoted terminology is not present, it is inserted by the clerk. **Each claim begins with a capital letter** and ends with a period. Periods may not be used elsewhere in the claims except for abbreviations. See *Fressola v. Manbeck*, 36 USPQ2d 1211 (D.D.C. 1995). \*\* Where a claim sets forth a plurality of elements or steps, each element or step of the claim should be separated by a line indentation, 37 CFR 1.75(i).

b) Claim 56 is vague and indefinite in that it is not known what is meant by the capital letter "G" in Group, see the fourteenth line of page 15.

c) Claim 58 is vague and indefinite in that it is not known what is meant by the capital letter "G" in Group, see the fifth line from the bottom of page 22.

d) Claim 59 is vague and indefinite in that it is not known what is meant by "amindehydrochloride" in the nomenclature of the first species.

e) Claim 60 and claims dependent thereon are vague and indefinite in that it is not known what is meant by the capital letter "G" in Group, see the fifth line of page 30.

f) Claim 70 is vague and indefinite in that it is not known what is meant by the capital letter "G" in Group, see the third line from the bottom of page 38.

g) Claim 71 is vague and indefinite in that it is not known what is meant by the capital letter "G" in Group, see the seventh line from the bottom of page 46.

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h) Claim 72 is vague and indefinite in that it is not known what is meant by the capital letter "G" in Group, see the fourth line of page 54.

i) Claim 73 is vague and indefinite in that it is not known what is meant by the capital letter "G" in Group, see the first line of page 62.

j) Claim 74 is vague and indefinite in that it is not known what is meant by the capital letter "G" in Group, see the seventh line from the bottom of page 66.

k) Claim 75 is vague and indefinite in that it is not known what is meant by the capital letter "G" in Group, see the third line from the bottom of page 73.

### Conclusion

Applicant's attention is directed to U.S. Patent No. 6,313,153, which while not competent as a reference against the instant claims, claims subject matter that is similar and/or identical to that claimed herein. Two patents cannot issue on the same subject matter, unless applicants can demonstrate that the claims are patentably distinct from the claims of this US patent, the only way to overcome this patent is by way of Interference proceedings or removal of the conflicting subject matter. See MPEP 2306.

The applicants stated in their remarks filed December 12, 2003 that claim 1 of this document wherein it is explicitly stated, that "AR<sup>1</sup> is not a 3-pyridyl group". However, it is not seen where this is stated and furthermore the species of 6,313,153 are to the 3-pyridyl group.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

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§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brenda L. Coleman whose telephone number is 571-272-0665. The examiner can normally be reached on 9:30-6:00 Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mukund Shah can be reached on 571-272-0674. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should



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you have questions on access to the Private PAIR system, contact the Electronic

Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in cursive script that reads "Brenda Coleman".

Brenda Coleman

Primary Examiner Art Unit 1624

March 17, 2004